

REMARKS

The examiner rejects claims 1-3 under 35 U.S.C. § 112, first paragraph, "because the specification, while being enabling for detecting a few fluids and distinguishing them from each other using few criteria, does not reasonably provide enablement for detecting every biological material and distinguishing it from every other material." Furthermore, the examiner argues that the "specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims." The inventors propose that Claims 1-3 be amended as shown in the claim amendments.

This amendment limits the biological materials (where the term 'biological material' is defined in paragraph [0003], line 2 of the specification [U.S. Patent Application 20040197771]) to those intrinsically fluorescent materials specifically disclosed in paragraph [0003] of said specification. Furthermore, the amendment limits the detection and differentiation between these materials to surfaces, as disclosed in both the Field of Invention [0002] and paragraph [0004] of the specification. The amendment further limits the biological material to those exhibiting intrinsic fluorescence (as disclosed in paragraph [0003]), claiming the detection of these materials and not broadly of other material associated with biology (e.g., water and the like). These limitations should better instruct one skilled in the art to practice the disclosed methodology.

Additionally, by limiting the scope of the claim to biological evidence expected to be found at a crime scene (as taught in paragraphs [0003] to [0005] and [0009] of the specification), it would be apparent to one skilled in the art that the 'biological material' to be detected would be of animal (principally human) origin. The underlying method, as taught in the specification

for the detection of biological evidence at a crime scene or in U.S. Patent Application # 20030138875 for the detection of microorganisms (of which the instant specification is a continuation in part), utilizes the similarities in the presence of intrinsic fluorophores inside in all target biological material while at the same time requiring that these fluorescent components be present within an expected distribution in the sample in question. Thus, the method cannot (nor does it claim to) distinguish between the blood of a human and any other animal (with the exception being that the method would be able to distinguish between human blood and blood from either supunculid peanut worms or horseshoe crabs that utilize oxo-bridged iron atoms and copper ions for oxygen transport in their blood, respectively.) Therefore, by using the specified fluorescence regions taught in the specification and by limiting the definition of biological material to that in paragraph [0003] and the amended claim, the claims better describe the practice of the disclosed invention.

Practice of the invention is further clarified through amendment to claim 1, parts (d) – (f), wherein steps for the detection of the presence of any material are now shown. The steps to distinguish between the specified and limited biological evidence on surfaces, as provided in the preamble of the amended claim 1, is now appropriately contained in claim 1. Even though it is well known to those skilled in the art that the amount of fluorescence emission obtained upon excitation depends upon the amount of material present,¹ and that emission intensities are correlated to excitation intensities, all references to quantitation have been removed from claim 1. The amended claim should now provide guidance for distinguishing between samples, including that for saliva and skin oil (which lacks the emission between 630 and 700 nm) as disclosed in paragraph [0003] of the specification.

¹ See Chapter 2 of the quintessential work on fluorescence spectroscopy "Spectrochemical Analysis" by J. D. Ingle, Jr. and S. R. Crouch (pub. 1988 by Prentice-Hall, Englewood Cliffs, NJ).

The amended claim 1 clarifies other points identified by the examiner as explained below:

- The amended claim 1 now utilizes the term “distinguishing between” instead of differentiation to clarify the claim as requested by the examiner.
- The amended claim 1 now provides an antecedent basis for the terms ‘intrinsic fluorophore’ and ‘biological fluorophore’ as requested by the examiner.
- The amended claim 1 now provides antecedent basis for the term ‘the signal intensities.’
- The amended claim 1 now provides antecedent basis for the term ‘the background intensities’ and describes the way it is determined as contained in the specification (paragraphs [0004] and [0012]).
- The amended claim 1 now provides the antecedent basis for the term ‘reflectance and scattering’ and the basis of the subtraction of their values as determined from intrinsic fluorophore minima values from the intrinsic fluorophore maxima values. References to any ‘algorithm’ are removed from the claim in the amendment.
- The amended claim 1, in an effort to avoid confusion, now contains the steps to distinguish biological materials.

As claim 2 has been withdrawn, the examiner’s comments concerning this claim have not been included in this response.

Claim 3 has been amended to address the examiner’s concerns in the following manners:

- The amended claim 3 now clearly describes the fluorescence emission ranges from the excitation ranges, and
- The amended claim 3 now indicates which biological materials are identified through which fluorescence excitation and emission ranges.

When allowable subject matter is determined applicants will address the issue and take care of any necessary amendments dealing with the double patenting issue raised by the Examiner.

The examiner rejects claims 1-3 under 35 U.S.C. § 102(b) as being anticipated by Powers (both U.S. Patents 5,760,406 and 5,968,766). Though Powers does utilize excitation wavelengths in the 350 – 390 nm region (col. 3, lines 30-34), and is able to distinguish microbes growing on meat or poultry from the cells comprising said meat or poultry (col. 5, lines 21-41), these specifications utilize the excitation and emission of a single microbial metabolite NADH (a high-energy reduced molecule that is unlikely to be present in any significant amount in a non-living biological material that is dried and exposed to oxygen for any length of time) and not numerous fluorophores. Furthermore, these patents utilize the *ratio* between the fluorescence and the reflected excitation light (col. 4, lines 66-67 to col. 5, lines 1-3), and do not teach the subtraction of background, scattered excitation light (which will occur at lower energies than the reflected excitation energies), nor the use of utilizing the presence and ratios of multiple corrected fluorescence emission signals for the differentiation (paragraph [0003]) between biological materials.

The examiner rejects claims 1-3 under 35 U.S.C. § 102(b) as being anticipated by Ho (U.S. Patent 5,701,012). Though Ho teaches the detection of multiple microbial fluorophores (NADH and riboflavin), it differs from the instant application in three important ways.

First, Ho teaches the use of filters for the removal of UV light that has been scattered by the outer nozzle of the borosilicate aerosol dilution tube and *not* from the sample (col. 6, lines 55-58). (Ho teaches no method to account for the scattered excitation light in the sample that passes through the aperture of the Schott filter.)

Second, Ho teaches the determination of the background of their detection system when they disclose, "Prior to each test, a background fluorescence population was determined... (col.

10, lines 66-67)." It will be appreciated by one skilled in the art that this method would measure the background at a time when no sample was present; this is hardly teaching the determination of the background (as defined in the instant specification as the amount of signal present in the absence of excitation energy) of the sample itself.

Third, since Ho discloses a method for distinguishing airborne microbes from inert dust (col. 3, lines 1-4), it utilizes the determination of the particles size (since microorganisms have different sizes from dust, fungi, pollen and the like). Since the instant application describes the detection of biological material on surfaces, particle sizes are not useful for distinguishing between the material of interest and the substrate surface. The instant application relies on utilizing the presence and ratios of multiple corrected fluorescence emission signals for the differentiation between biological materials.

It is believed the claims are now in condition for allowance, which action is respectfully requested. Should the Examiner have any questions, he is requested to call Applicants' undersigned attorney collect at (801) 521-3200.

Respectfully submitted,



K. S. Cornaby
Attorney for Applicants
Jones Waldo Holbrook & McDonough PC
170 South Main Street, Suite 1500
Salt Lake City, UT 84101
(801) 521-3200

CERTIFICATE OF FACSIMILE TRANSMISSION

I hereby certify that the attached Amendment is being facsimile-transmitted to Examiner
Lora E. Barnhart, Commissioner for Patents, Washington, D.C. fax (571) 273-8300 on the 21st
day of June, 2006.

Roberta M. Kelly